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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,733	12/21/2004	Geoffrey Phillip Dobson	36749-212211	1333

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

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07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,733	DOBSON, GEOFFREY PHILLIP	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-49* is/are pending in the application.

4a) Of the above claim(s) *35-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/04, 7/13/05,*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-49 are pending. Claims are 30-34 considered on the merits. Claims 35-49 are withdrawn from consideration as being drawn to a non-elected invention.

Please note that applicant's Australian priority document has not been included on the Bibliographic Data Sheet. Please request a corrected filing sheet which includes Australian foreign priority document.

Election/Restriction

Claims 35-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 4/30/07.

Applicant's election with traverse of Group I in the reply filed on 4/30/07 is acknowledged. The traversal is on the ground(s) that Groups I and III share a common technical feature. This is not found persuasive because the restriction requirement mailed 3/39/07 clearly demonstrated that unity of invention is not present in the instant claim set because there is no uniting SPECIAL TECHNICAL FEATURE, see page 4 of the restriction. The requirement is still deemed proper and is therefore made FINAL.

It is noted that rejoinder of method claims to an allowable composition may require a terminal disclaimer over copending 10/539222 and other copending applications.

Specification

The disclosure is objected to because of the following informalities: -chloropyrazine- is misspelled on page 10, line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 31 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 uses abbreviations which have not been defined in the claims. Please do not use abbreviations in the claims as abbreviations may permit unfavorable interpretations and are not clear as to what compound is meant, especially without definition. "B11 B-513" cannot be found in the Chemical Abstracts Registry File which is a registry of all known compounds. Thus, the claim is rendered indefinite by this recitation. It is unknown what is meant by "cariporide (HOE-642)". HOE 642 is not "cariporide". Thus, the meaning of the parenthetical inclusion is not understood. Is it meant to further limit or expand the preceding term or is the preceding term incorrect. Why is "Triamterene" capitalized? Is it a proper term or a trade name. If it is a trade name, it should be treated as such.

Claim 34 recites "in an amount for increasing the amount of magnesium in a cell in the tissue" and "in an amount for decreasing the amount of calcium within a cell in the tissue". This is indefinite because the tissue is not stipulated and, therefore the "amount" (concentration?, mass?) depends on a variable. See MPEP 2173.05(b), *Ex parte Brummer*, 12 USPQ2d 1653.

Please correct the spelling of -chloropyrazine- in claims 31, 32.

SCOPE

Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, while being enabling for a composition comprising specific A1 or A3 adenosine receptor agonist, lignocaine, diazoxide when limited to an *in vitro* perfusion solution, does not reasonably provide enablement for the composition containing any adenosine receptor agonist (elected species) to be an *in vivo* composition which controls the viability of a tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The invention is a composition comprising an adenosine receptor agonist (elected species) or potassium channel opener in combination with other components such as an anesthetic and a sodium ion/proton transport inhibitor. The composition is both an *in vitro* and an *in vivo* composition.

The working example is limited to a composition used *in vitro* in a perfusion method which comprises adenosine (which according to the specification on page 13, is a potassium channel opener and is not defined as an adenosine receptor agonist), lignocaine, diazoxide and other components, see example 1. Thus, the working example cannot provide support for the enablement of the instantly claimed composition.

Ulusal *et al.* [U], which publication demonstrates the state of the art in 2006, disclose that the administration of an adenosine receptor agonist to an animal (*in vivo*) which has had an allotransplant, has no effect on the prolonging the transplanted tissue, that is, controlling the viability of a tissue. Therefore, this reference teaches the ineffectiveness of the administration of an *in vivo* administration of an adenosine receptor agonist to preserve viability of tissue.

Further, Neely *et al.* [V] teach that administration of adenosine receptor ANTAGONISTS significantly reduce ischemia and may be useful in cardiac transplant surgery; however, administration of adenosine or adenosine agonists prior to ischemia appears to be beneficial. Ischemia/reperfusion injury is associated with transplantation of organs among other medical situations. Thus, the timing of the *in vivo* administration of the composition containing the adenosine receptor agonist appears to be critical. The specification is silent with regard to this issue.

US 6,586,413 [A] teaches that there are different kinds of adenosine receptors such as A1, A3, A2a, while activation of A1 and A3 provides benefits to ischemic cardiac cells, activation of A2a is deleterious (col. 7, l. 52-57).

Thus, this shows that not all receptor agonists function to preserve tissue function which is the disclosed utility of the claimed invention. The claims are not fully enabled over their scope.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in In re Fisher, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. Ex parte Humphreys, 24 USPQ2d, 1260.

Double Patenting

Claims 30, 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,955,814 [B]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed composition encompasses and is coextensive with the issued composition claims. US 6,955,814 claims a composition, in one embodiment, comprising: adenosine receptor agonist, anesthetic and potassium channel opener or agonist of which an AV blocker is one class. AV blockers are a group of compounds of which verapamil is one (col. 4, l. 25) of the issued patent. Verapamil is also a sodium ion/proton transport inhibitor (see Segal *et al.* abstract [W]). Thus the issued patent composition claims read on the pending composition claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 00/56145 [BA] in light of Segal *et al.* [W].

The claims are directed to a composition comprising:
a) potassium channel opener OR an adenosine receptor agonist,
b) a local anesthetic,
c) an inhibitor of Na+/H+ membrane transport.

WO 00/56145 discloses an embodiment of a composition comprising: a potassium channel opener and an adenosine receptor agonist and an anesthetic, claim 26. The potassium channel opener may be an AV blocker (claim 29). An AV blocker may be verapamil (page 6, l. 6). Verapamil also has Na+/proton transport inhibitor activity (Segal *et al.*). Thus all claimed activities are present in the composition.

The species election of a) adenosine receptor agonist and c) N-amidino-3,5-diamino-6-choloropyrazine-2-carboximide HCL dehydrate is acknowledged. The above rejection is made in order to demonstrate that the generic claim is not allowable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/56145 [BA] in combination with US 5,693,462 [AI].

The claims are directed to a composition comprising:
a) an adenosine receptor agonist,
b) a local anesthetic,
c) an inhibitor of Na+/H+ membrane transport (N-amidino-3,5-diamino-6-choloropyrazine-2-carboximide HCL dehydrate).

WO 00/56145 discloses a composition comprising an anesthetic such as lignocaine, an adenosine receptor agonist and diazoxide as K+ channel opener to protect/preserve organs. The reference is missing the inclusion of the specific compound N-amidino-3,5-diamino-6-chloropyrazine-2-carboximide HCL.

US 5,693,462 discloses inclusion of about 1-5 μM amiloride or amiloride analog to a solution to preserve organ function (col. 5, l. 28-42). Inclusion of amiloride in preservative solutions is effective in increasing storage time and lessening injury to the organ (col. 2, ls. 60-67, col. 3, ls. 1-3).

One of ordinary skill in the art would have been motivated at the time of invention to make this addition in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL

disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651